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Capturing Value from Health Technologies in Lean Times

Developing new healthcare technology is a risky business for drug firms, medical researchers and makers of diagnostic equipment. Health Technology Assessment provides decisionmakers with a tool to ensure the benefits for society outweigh the costs of adoption.

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The Study In Brief

The adoption of new health technologies brings potential improvements to quality of life as well as new costs for provincial healthcare systems. An appropriate evidence-based framework for adoption decisions therefore can go a long way to improving value for money in our health systems. While making decisions to adopt new technologies is a highly politicized process, these decisions must nonetheless strive to make use of all available evidence, including economic evaluations that consider all the costs and consequences of new technologies for society as a whole, including medical, ethical, legal, social and cultural.

This *Commentary* focuses on an emerging, evidence-based policy tool called Health Technology Assessment (HTA). HTA helps inform decisionmaking on how to balance demand and supply pressures for new technologies within a health-system budget. The overarching objective is to obtain the greatest health gains within fiscal constraints by grounding decisions in a clear, transparent and coordinated process.

In Canada, the number of entities engaged in various forms of HTA has been growing, and more and more people in healthcare are becoming exposed to the techniques involved. This progress and capacity growth is encouraging. However, rather than counting on a natural slowing of healthcare costs to relieve fiscal pressures, the provinces would be better off grounding their efforts in clear and coordinated HTA processes that incorporate economic evaluation and meaningful collaborative deliberation based on available evidence.

This *Commentary* also looks at examples of HTA experience outside Canada and highlights lessons for Ottawa and the provinces. At present, the National Institute for Health and Care Excellence in the UK is by far the most advanced example of an attempt to utilize a consistent framework for technology adoption in a government-funded healthcare system. The UK's current transition toward "value-based pricing" is another positive example of how HTA economic evaluation can be used to inform technology adoption in a more constructive way than with traditional "yes" or "no" recommendations.

Canadian HTA agencies should draw as much as possible on existing international evidence – from randomized clinical trials, post-market assessments, clinical guidelines, etc. – and maintain close relationships with their counterparts in other countries and international organizations. Finally, HTA frameworks in Canada also must aim to encourage greater stakeholder participation and relationship development.

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Healthcare costs in Canada have, on average, been growing faster than the overall economy for many decades.

One reason is the system's increasing human resources costs, which result in part from the healthcare sector's slow productivity growth (Baumol 2012). But studies of healthcare costs in a number of countries typically identify another explanation: the cost of advancing medical technology (Chernew and May 2010, Dodge and Dion 2011, CIHI 2011). When coupled with an aging population, this effect may worsen as age-associated utilization of technology grows.

However, introducing new treatment methods, devices, drugs and vaccines yields valuable health benefits to society. For example, new techniques for treating heart disease are believed to have been the main reason why estimates of life-expectancy at birth in the US between 1960 and 2000 rose by more than seven years – from 69.6 to 76.9 years (Cutler et al. 2006). Similarly, hip and knee replacements are routinely used to enhance quality of life, especially for elderly patients who would otherwise have to live with lower functioning and chronic pain.

The value of longer life expectancy and improved health-related quality of life for the elderly are not reflected in conventional measures of national income and average living standards. However, human welfare gains from reduced mortality and improved health have been estimated to be of comparable magnitude to conventionally measured economic growth in raising living standards over time (Murphy and Topel 2006).

Health technology assessment (HTA) is an evidence-based policy tool that helps inform decisionmaking on how to balance demand and supply pressures for new or existing technologies within a health-system budget. Through HTA, efforts to obtain the greatest health gains within overarching fiscal constraints can be grounded in clear, transparent and coordinated processes that incorporate economic evaluation and available evidence. Over time, the focus and results of HTA should expand to include best practices and clinical guidelines in addition to new drugs and medical devices.

This *Commentary* advocates a structured, transparent and inclusive use of HTA that is timely and relevant to decisionmakers, and examines the international experiences with HTA systems. On this latter score, the authors believe that recent reforms in the United Kingdom, which uses evidence-based assessments to inform pricing decisions for new technologies rather than saying yes or no to a particular technology based on its cost, are a practical demonstration of how empirical evidence can be effectively used to manage healthcare technology. Furthermore, recent international efforts to coordinate HTA activities and reduce unnecessary duplication should inspire Canadian provinces as they seek to reduce the proliferation of provincial and hospital-level HTAs.

Health Technology Assessment: Capturing Value from New Technology

While there are many instances where new technologies yield benefits that clearly outweigh the

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cost of developing and using them, there are also many examples where they have not. Indeed, the development of new technology – by drug firms, medical researchers and manufacturers of medical and diagnostic equipment – is a risky business. New drugs or treatment methods may turn out to have side effects that outweigh their direct benefits, or they may be difficult to administer. More commonly, their advantage over existing technologies – in terms of improved patient outcomes, higher diagnostic accuracy or reduced side effects – may be smaller than hoped for, and the cost of using the new technology may be higher than anticipated.

Even in cases where a technology does have additional health benefits compared to existing ones, it may not be worth using it if the cost is too high. With limited budgets, spending more on treating patients with a new technology means less money for treating others with older technologies, even though the latter may produce more health benefits per dollar spent.[1]

As the healthcare sector eats up a larger and larger share of total economic resources, systematic assessments to promote more cost-effective use of technology can help reduce resource waste and obtain better value for money spent.[2]

In this *Commentary*, we briefly describe different approaches to HTA and review the way they have been used in Canada and other countries. We conclude that a more systematic use of HTA, properly structured, could be an effective way to better control the growth in aggregate new technology-related healthcare costs and provide better value for limited healthcare dollars.

HTA Defined

Health technology assessment, broadly speaking, refers to the evaluation of a new technology's impacts – medical, ethical, legal, social and cultural – and examining whether these impacts justify the costs of adoption.

Clearly, systematic collection of evidence and information on the costs and consequences of new technology is central to this process. This is a high-stakes game. The producers, individuals and firms, who have developed the technology, want it to work well and be widely used. Most of them – pharmaceutical firms and manufacturers of diagnostic and medical devices – have a strong financial interest in seeing this happen. On the consumer side, patients and their doctors want to know the technology's health benefits. And third-party payers, such as provincial governments or private insurers, are particularly interested in the technology's costs in relation to policy-relevant outcomes when deciding whether they will agree to pay for using it. While we conclude that HTA can help address the difficult choices that must be made, the issues surrounding the development and use of HTA are complex and worth exploring in detail.

1 Higher healthcare spending also has a broader societal opportunity cost: as we devote more and more of the economy's resources to the healthcare sector, there is less available for other valuable goods and services such as better housing and education. In Canada, since most of healthcare costs are paid by the provinces, the rising opportunity cost of healthcare has translated into increasing strains on provincial governments' finances.

2 The idea that we could get better value for money in healthcare is commonly voiced among sector insiders, but formal estimates of healthcare inefficiencies are rare. One report by the World Health Organization estimated that around 20 percent to 40 percent of all healthcare expenditures could be saved through efficiency improvements (Chisholm and Evans 2010). Another recent report by the American Institute of Medicine suggests that as much as 30 percent of total US healthcare spending in 2009 was wasted (Smith et al. 2013). Some of the factors giving rise to inefficiency identified in these reports don't apply in Canada, but Canadians will recognize many of the other factors cited.

HTA: From Whose Point of View?

Approaches to HTA vary in different settings and by different agencies. In general, HTA processes are based on an evaluation of policy relevant consequences – especially expected clinical outcomes and cost – of a new technology in comparison with current and widely used alternatives. The comprehensiveness of the analysis varies according to the needs of individual decisionmakers. Some HTA processes may be limited to a technical review of one or more aspects of new technologies, such as clinical effectiveness in terms of producing beneficial patient outcomes or reducing side effects, but with little consideration of cost relative to available alternatives. If costs become part of the analysis, they are typically defined and measured from the perspective of the body making the funding decision.

For example, when a hospital is deciding whether to acquire an expensive piece of equipment that enables its surgeons to employ a newly developed technique for heart operations, the focus may be on the hospital costs in acquiring and operating the equipment and not on the broader health system costs of managing cardiac patients. A comprehensive economic evaluation would consider all the costs and consequences of new technologies, taking the viewpoint of society as a whole.

As we discuss below, few countries today include a societal perspective when evaluating alternative technologies. Moreover, such a more comprehensive approach sometimes causes considerable controversy. One issue is that the more an economic analysis is based on a societal, rather than a payer's, perspective, the harder it is to tie the results into the day-to-day decisions of those responsible for particular health budgets.

HTA processes may also vary according to the degree they are linked to decisionmaking. They can range from simply providing information to the decisionmakers to a more comprehensive process that engages with clinicians, patients, health-system budget holders or research funders. While some HTA bodies produce research reports, others also offer recommendations, clinical guidelines or educational activities for patients and providers.

Typically, HTA bodies are asked to focus on informing new technology adoption decisions, as these are easiest to implement. At the same time, they are increasingly focusing on evaluating existing technologies, as a means to remove wasteful expenditures on older technologies whose value has never been assessed.

Why is HTA Controversial? The "Rationing" Issue

Some of the most controversial HTAs are those undertaken by official or semi-official agencies linked to large government health-financing programs, such as the National Institute for Health and Care Excellence (NICE) for the National Health Service (NHS) in the United Kingdom, or the Australian Pharmaceutical Benefits Advisory Committee (PBAC) for the Pharmaceutical Benefits Scheme (PBS) in Australia. These agencies are potentially useful instruments for controlling aggregate healthcare costs since they are intended to formulate policies – such as restricted formularies or clinical guidelines – that effectively prevent doctors and hospitals from approving treatments with drugs or technologies that the agencies have deemed insufficiently effective or too costly in comparison with existing approaches.

However, these approaches generate controversy when they reject new drugs or treatment methods. The developers stand to lose large amounts of potential revenue and the patients who hope to benefit are prevented from using them; as a result, patients may complain that healthcare is "rationed." For their part, doctors may argue that HTA guidelines restrict their rights, under the principle of clinical autonomy, to offer the care they deem best and medically necessary.

Clearly, HTAs that say "no" to choices that patients and doctors would make if they could, are bound to be contentious. But from the viewpoint of society as a whole, "no" may be the right

answer because the associated costs represent lost opportunities for additional health gains for other patients who would benefit from more cost-effective spending. (Box 1 highlights the tradeoffs involved in financing the development of new technologies and assessing their benefits or harms.)

Concerns by patients, providers and technology producers with HTA-based policies that restrict new technologies are also understandable because such restrictions seem specific to healthcare. After all, in other sectors governments generally do not restrict consumer access to new technologies, or the right of sellers to offer them. For example, when new technologies were developed that enabled car manufacturers to add features such as anti-lock braking systems, air conditioning or global positioning systems, the only "assessments" typically undertaken were in the form of specialty magazine reports telling consumers how well the technologies worked and how much they added to the price of the car. It was then left to those who buy cars to decide for themselves whether paying for the new technology was worth it.

But this analogy neglects a fundamental fact of healthcare systems in Canada and other advanced countries: most health-service costs are not paid directly by the patients who receive them, but through pooled risk-sharing agreements managed by third parties. In Canada, this is done largely by provincial health insurance plans for hospital and physician services and public or private insurance plans that pay for drugs. To individual patients and their doctors, technologies involving drugs or services that promise to offer even slightly better outcomes usually seem the better choice even if they are very costly, because the cost is paid mainly by somebody else.[3] Failure to recognize this dynamic may well have been a major reason for rapidly rising healthcare costs in many countries in the past, the United States in particular. But this highlights the need for credible HTA processes that can identify technologies offering incremental health benefits that are too small to justify their high cost.

A Critical Question: How Do We Measure Benefits From New Technology?

Controversy sometimes also arises from other aspects of the way a given technology has been assessed, including the choice of alternatives against which it is compared. Another major challenge has been to create methodology that quantifies potential benefits – such as improved (health-related) quality and length of life. In recent decades, however, progress has been achieved in constructing measurements for the value of different types of health improvement, both in relation to each other and in comparison with other goods and services. The general measure of health that has gained the widest acceptance is the quality-adjusted life-year (QALY).[4,5]

A QALY represents one year of life lived in a perfect state of health. (See Box 2). The strength of using additional QALYs as a measure is that they reflect a large range of benefits that healthcare is supposed to produce, from saving the lives of people with potentially fatal conditions, to improving the quality of the lives of those

3 While it is true that potential beneficiaries also pay taxes, the dilemma we are referring to here is closely associated with "the tragedy of the commons," when individuals act in their own immediate self-interest and contrary to the group's long-term interests. See Hardin (1968).

4 See http://www.nice.org.uk/newsroom/features/measuringeffectivenessandcosteffectivenesstheqaly.jsp for a more thorough definition of the concept (Date of access: June 17, 2013).

5 To qualify, there is not universal acceptance of QALYs as the empirical basis for economic assessments. Germany, for example, uses a different, but theoretically similar, criterion in its approach.

Box 1: Is HTA a Disincentive to Research and Innovation?

Development of new medical technology can be very costly. In the debate about HTA, technology developers have pointed to regulatory requirements to conduct large and lengthy trials to demonstrate the benefit-harm balance of new technology as a significant cost driver and cause of delay. Similarly, restricting the funding of new technology based on its costs to health-system payers may reduce developers' expected revenues and future R&D spending.

This raises a profound question: In our quest for safety and better value for money, will we inadvertently harm society by slowing down the development of new technology that would benefit patients and improve human welfare?

With respect to safety regulations, it is now widely recognized that standards can be set at too high a level. While setting high standards reduces the risk of unexpected side effects, it also delays the benefits of the introduction of new technologies that may be useful or needed by patients. Striking a balance is not easy. Different countries may set somewhat different safety standards, but can learn from each other's experiences. Safety standards are, however, usually rooted in regulatory regimes and often outside the scope of the HTA process.

With respect to the impact of economic evaluation on the financing of research and development, restrictions on the use of new drugs that fail a cost-effectiveness test implies reduced revenue for the firms that have developed them. Indirectly, low threshold values for the maximum acceptable cost per QALY, for example, reduce the expected return from developing technologies and make it harder to attract financing for new research and development.

However, if the threshold value for the cost per QALY has been set appropriately, using a technology that does not meet this standard implies some degree of waste of resources and money. The incentives for spending money on research and development of a new technology can be directly enhanced in less wasteful ways. For example, the technology may be granted a longer period of patent protection, which increases the expected revenue from successful innovations, or through direct subsidies for research and development spending through the tax system.

It should also be noted that the revenue new technology developers earn from the Canadian market typically is only a small portion of their total earnings; most new technology is marketed throughout the world, not just in Canada. Thus, the impact of Canadian rules for economic evaluation of new technology would have only a minor impact on worldwide incentives to develop. Canada can signal its commitment to supporting global research and development in other ways, for example, through support for consistent enforcement of rigorous intellectual property protection in all countries.[a]

a It is sometimes argued that rules that lead to higher earnings in the Canadian market (for example, by pharmaceutical companies) will cause them to undertake more research here, rather than in other countries. It is not clear what the basis for this argument is, since there is no obvious link between the expected worldwide revenue from a successful innovation, on the one hand, and where the R&D has been done, on the other hand.

with less serious conditions that cause disability, pain, and discomfort. In principle, QALYs can be used to measure the benefits of any kind of health intervention, and these benefits can then be compared with their estimated costs in order to decide whether the new technology should be classified as a cost-effective alternative to older ones.

Threshold Values and Value-based Pricing

How much should a healthcare system be willing to pay to produce an additional QALY? In some countries, health economists have proposed specific critical values for upper limits on what society is willing to forego in order to produce an additional QALY. These values are intended as a "threshold" such that technologies with a QALY cost above this level are not recommended for general use, and reflect the budgetary constraint under which the system operates (Buxton 2005). For example, the United Kingdom has adopted a £30,000 ($52,000) threshold per QALY.[6] An established threshold value can help system administrators decide whether to purchase a technology that is offered at a given price.

In the past, developing threshold values for additional QALYs resulting from new technologies was typically done to guide adoption decisions based on the manufacturer's listed price. More recently, threshold values have increasingly been used as a tool to inform price negotiations between the new technology developers and third-party payers (Husereau 2011a, Husereau and Jacobs 2013). A threshold value for an additional QALY is implicitly a measure of its value to the payers and society, providing the developers an incentive to price new technology at a level that meets this value. The term "value-based pricing," introduced after a review of UK new technology pricing policies, is now widely used in the HTA community and also includes a basis for pricing new medicines. Indeed, the United Kingdom is reforming its current pharmaceuticals pricing system from one based on profit control to a value-based system that will determine what prices should be paid based on such an economic evaluation.[7]

In other words, rather than use HTA as a tool to say yes or no at a given price, it will be used to set the maximum acceptable price, based on the evidence of how many additional QALYs are created in comparison with the best available alternative. The UK Department of Health and the Association of the British Pharmaceutical Industry (ABPI) are pledged to introduce value-based pricing "in a planned and progressive way" with a focus on new medicines placed on the market from January 2014 (UK DoH 2011). More recently, these bodies announced an interim process will be introduced in January with a final process expected in September 2014.

When HTA-based approaches are used to negotiate a price for the use of a new technology, as part of an agreement to approve it, this implies an assessment process that is less unilateral than a simple yes-no decision; it also removes some of the uncertainty that technology developers face in generating revenue to finance further R&D. A further development in this direction is negotiation

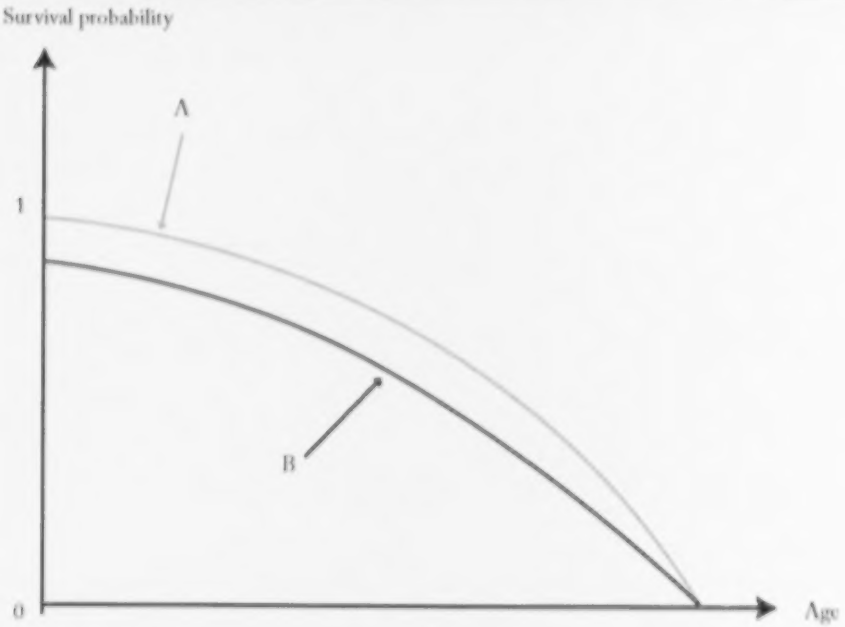
6 Readers may be concerned that this kind of threshold value specification is arbitrary. However, the method can be related to empirical work on how much individuals appear to value reductions in the risk of accidental death. A central concept in this work is often referred to as the "Value of a Statistical Life" (VSL). That said, there are examples of listed technologies that exceed the critical threshold, exemplifying that many factors surround the use of HTA results in decisionmaking.

7 Additional issues related to implementation, including what medicines should be subject to a value-based price (e.g., all new entrants after implementation or all medicines) are also being considered.

Box 2: Quality-Adjusted Life Years

The quality-adjusted life-year (QALY) is a generalization of the concept of life expectancy, the summary statistic of a population's mortality rates. Life expectancy at birth (around 80 years in Canada, at present) can be thought of as the average age at death or, equivalently, the average number of years that a newly born individual will live if he or she is subject to the average risk of death in the population at every age. In a diagram with age on the horizontal axis and survival probability on the vertical, life expectancy can be measured as the area under a curve that shows, for each age, the probability that a newborn individual will be alive at that age. In Figure 1, curve A is the survival probability, and life expectancy can be approximated by the area under that curve.

Figure 1: QALY and Life Expectancy



Conventional life expectancy is area under curve A;
Quality-adjusted life expectancy is area under curve B.

Source: Authors' illustration.

In computing life expectancy as conventionally defined, one implicitly weights every year that an individual is alive in the same way, regardless of the (health-related) *quality* of the person's life. In computing the quality-adjusted life expectancy in a population, in contrast, a lower weight is given to lives lived by people whose quality of life is significantly impaired because they have health problems, such as disabilities or various kinds of illness.

Box 2 cont'd on next page.

Box 2: Continued

If one recognizes that years of healthy life are lost in populations not just because some people die, but also because some live with conditions that reduce the quality of their lives, one can construct curve B in Figure 1 so that it takes into account both factors. Specifically, at any age, curve B considers all individuals who suffer from conditions that significantly reduce their quality of life and weights their lives by a factor $b < 1$. The precise value depends on the seriousness of their condition and is smaller the more serious their disability or illness.

Curve B must lie below curve A as long as not every living individual is in perfect health. The distance between them will reflect both the number of individuals in the population who live with illnesses or conditions that significantly reduce the quality of their lives and the seriousness of their conditions. For a given population, the area under curve B then measures "healthy life expectancy," that is, the average number of healthy life-years a person in this population can be expected to live, taking account not only of mortality but of morbidity as well. Area Y is a measure of the loss of healthy-life expectancy as a result of the fact that not all individuals who remain alive are in good health.

Conventional and healthy-life expectancies can be computed for any population, starting from any age (for example, 65). They can also be estimated for populations with specific types of illness conditions such as persons diagnosed with diabetes or men diagnosed with prostate cancer.

For given populations, interventions that reduce mortality or improve patients' quality of life have the potential to shift the curves upward. If mortality is reduced at any age, both curves will shift upward, increasing both ordinary life expectancy and the expected number of QALYs in the population. If an intervention improves certain patients' quality of life but does not affect mortality, curve A (and hence ordinary life expectancy) will be unchanged, but curve B will shift up, reflecting an increase in quality-adjusted life expectancy.

In principle, every time an HTA estimates a QALY-gain for some specific population, the net effect can be represented as the area between two B curves, one without use of the new technology, the other with it. The fact that the benefits of any new health technology can be represented in this way is what makes it possible to consistently compare the cost-effectiveness of different innovations, whether they result in reduced mortality, improved quality of life or both.

The biggest challenge in applying this methodology consists in finding plausible ways of assigning weights (the b-values) to the value individuals put on living with health problems and conditions that reduce the quality of their lives, in comparison with living healthy lives. A great deal of work has been done in recent years to respond to this challenge, and the trend toward wider acceptance of the resulting methodology seems clearly established.

of price-volume agreements between developers and payers. Under such arrangements, the per-unit price for using new drugs or technologies depends on the volumes purchased, with lower prices per unit as volumes increase. As observed below, price-volume agreements have been used in Canada and elsewhere to further reduce uncertainty about revenues developers will receive and the total costs to payers.

Real-world Effectiveness and Adaptive Approaches

Development of diagnostic technologies and devices are characterized by an ongoing process in which early prototype versions don't work as well as later ones and are more expensive to produce. For drugs, additional evidence of effectiveness in real-world clinical settings is generated through post-market evaluations after the drugs have been used for some time.

The dynamic nature of healthcare technology development, and the gradual accumulation of new evidence on its effectiveness, underscore the need for a flexible HTA approach and for prior agreements between technology developers and payers. For example, the appropriate course of action for a technology when the initial evidence shows limited benefits may be to approve it for use under an agreement that stipulates a low price, but with the understanding that the price will be raised if evidence from post-market evaluations shows more benefits than found initially. As another example, the fees approved for services supplied with a new medical device may initially be set at a level that reflects the relatively low productivity of the device's early versions. After a few years of use, later versions can be developed that lead to productivity improvements (Husereau 2011b) and, as a result, revisions in price or fee amounts.

The uncertainty that results from technology development's dynamic nature must be managed so as to leave room for the accumulation of further evidence after acceptance and for a subsequent review of initial price agreements. On this score, a comprehensive HTA process is best thought of not simply as a binary method of decisionmaking, but also as an adaptive process that revisits decisions: it is a tool to manage the use of healthcare technologies throughout their life spans.

Another Consideration: One Size Doesn't Fit All

When new technologies are developed for patients with particular health problems, they may end up being useful for some patients, but not for all of them. As any doctor knows, there are large differences in the effectiveness of particular drugs or treatment methods depending on the characteristics of individual patients. This heterogeneity creates difficulties for both the evaluation of new technologies and for the development of guidelines to help physicians decide how they should best treat patients.

Clinical practice guidelines can strongly influence what technologies will be used, yet they typically do not consider cost-effectiveness or opportunity costs. This explains the stark contrast in recent recommendations by two expert groups for the use of self-monitoring with blood-glucose testing strips by patients with diabetes. Examining roughly the same body of clinical evidence, two clinical committees made vastly different recommendations on who should use the strips. A patient-advocacy group considering clinical evidence alone initially recommended an open-use policy, and that patients should use the technology according to their needs (CDA 2011). For its part, a payer-led group concluded that only certain patients should be provided access to the technology, as this would free resources for other investments without compromising population health (CADTH 2010). Given this tension, Ontario recently revisited its policy, moving from an open-listing policy to a more restricted compromise between the two positions – one of limiting, rather than fully denying access to this technology (Ontario 2013).

This example highlights another conceptual limitation in the simplest forms of past economic evaluation and use of clinical evidence – saying "yes" or "no" is a blunt instrument for policymaking and is wrongly based on the assumption that all individuals will respond similarly to a new technology. There are often individual exceptions to this – particular patients who respond very well or not at all – that highlight the limitations of using population averages for policy decision-making. In some cases, access to new technology is provided in many jurisdictions on a case-by-case basis. However, these cases must be adjudicated by an administrator and can lead to additional costs. To account for the possibility of individual exceptions, most HTA bodies have developed "recommend-with-restrictions" criteria based on population subgroups for whom a drug or device is more cost-effective. Australia and the United Kingdom, for example, have developed strict rules on how effects in subgroups should be assessed in order to arrive at appropriate recommendations. Subgroup analysis coupled with economic evaluation allows policymakers to say "yes" for small populations without incurring high opportunity costs or exposing themselves to excessive risk.

In spite of the various controversies about both the development and use of HTA, its role in formulating healthcare policy has become more prominent in recent decades. In the next section, we review efforts that have been made to give HTA a more prominent role in the Canadian healthcare system and compare that experience with other countries.

HTA in Canada

All HTA systems, both in Canada and abroad, share similar characteristics in design and form. An assessment may be initiated by a manufacturer's application to a provincial plan to consider funding a new technology[8] or at the request of health ministry officials or health providers. Furthermore, to help decide if a new technology should be adopted, evaluations may include not only economic factors, but also social need and capacity to deliver, as well as ethical, legal and other important public-policy considerations. HTA processes are intended to support decisionmaking, but it is the decisionmakers who determine whether to use technology assessments and make recommendations for national, regional or local implementation.[9]

The Current Picture

Canada's joint federal and provincial roles in healthcare have created complex and overlapping HTA roles and responsibilities. A patchwork of HTA activity at local, regional, provincial and national levels exists with separate focuses on drugs and medical devices. Hospital-based and regional HTA bodies for drugs are commonplace, and similar approaches for medical devices are becoming more popular. For out-of-hospital drugs covered by provincial drug insurance plans, provincially based HTA approaches predominate.

Generally speaking, Canada's more wealthy and populated provinces tend to have greater HTA capacity, either at the provincial or local level (Table 1). Four provinces – Alberta, British Columbia, Ontario and Quebec – have created

8 This is mainly true for drug assessments. In non-drug assessments, HTA organizations often find other ways to initiate the process.

9 In some instances, like in Spain or Sweden, HTAs are used in federal-level reimbursement decisions and those decisions are binding on the otherwise autonomous sub-regional health systems.

province-wide HTA processes for medical devices. Hospital-based HTA programs are generally found in university and teaching centres, which are niche markets for new and expensive medical devices. There is a notable concentration of hospital-based HTAs in Quebec due to recent legislation requiring such a process.

Canada was an early leader in developing HTA bodies.[10] The Canadian Agency for Drugs and Technologies in Health (CADTH) was created in 1989 as an HTA resource with funding from federal, provincial and territorial governments. For medical devices, it acts largely as an information resource to all provinces except Ontario and Quebec who do no not pay for this service.

For out-of-hospital drug decisions, CADTH operates a drug review and recommendation process called the Common Drug Review (CDR) on behalf of federal, provincial and territorial drug plans. A similar provincially coordinated process, the pan-Canadian oncology drug review (pCODR) exists for oncology drugs. CDR and pCODR issue non-binding recommendations using expert committees that allow the provinces to make their own decisions on what drugs and devices to reimburse.

Both CDR and pCODR programs continue to be supported by provincial policymakers, although questions have arisen regarding the usefulness of these programs given the inconsistent adoption of their recommendations. Decisions to adopt new drugs may differ by province in part because of varying capacities to implement recommendations. Another reason for the differences is that many provinces have historically had the ability to negotiate prices or re-assess drugs within their own HTA programs that can consider local factors. This means a province with greater buying power can choose to list a new drug at a lower, and publicly undisclosed, price. The use of HTA results in Canada is changing as a result of a 2010 agreement by the Council of Federation, representing the provinces and territories, to develop a Pan-Canadian Pricing Alliance (PCPA) whose role is to examine opportunities to collaborate in price negotiations for drug products.

Limitations of Current Approaches

Even in the most influential among current Canadian HTA programs, few full-fledged economic evaluations are performed. Despite a formal remit to examine cost-effectiveness, a recent analysis of CDR decisions highlights the limited importance of this concept for listing recommendations (Rocchi et al. 2012).

Similarly, another examination of Canadian-based HTAs revealed a much smaller proportion of formal economic evaluations when compared to the United Kingdom and Denmark (Lavis et al. 2010). Within Canada, Ontario's province-wide HTA program, Health Quality Ontario, has an evidence development and standards division (formerly the Medical Advisory Secretariat) that produces economic evaluations at a much higher rate than the average among all provinces, presumably because it is closely linked to an overall health budget (Lavis et al. 2010). However, some evaluations in the study were only partial ones, such as a budget-impact analysis or a review of previous evaluations.

Meanwhile, hospital-based and regional HTA programs in Canada have pioneered more narrowly focused approaches to assess direct and opportunity costs within hospital and regional budgets (McGregor 2003, McGregor and Brophy 2005, Teng et al. 2007). Despite the importance

10 This includes both the international HTA society (HTAi) and network of HTA agencies (INAHTA), which are coordinated by the Institute of Health Economics, an Alberta-based HTA body.

Table 1: List of HTA Bodies by Province/Territory

Health System	Ministry	Local HTA (Payer Level)
Alberta	Alberta Health	Alberta Health Technology Decision Process (Province) Institute of Health Economics (Province) Health Technology Assessment Unit (Province) Health Technology and Policy Unit (Province)
British Columbia	Ministry of Health	Health Technology Review (Province) Centre for Clinical Epidemiology & Evaluation (Region)
Manitoba	Manitoba Health	None*
New Brunswick	Ministry of Health	Horizon Health Network HTA Program (Hospital)
Newfoundland and Labrador	Health and Community Services	Newfoundland and Labrador Center for Applied Health Research (Region)
Nova Scotia	Department of Health and Wellness	[In Development]
Nunavut	Health and Social Services	None
Ontario	Ministry of Health and Long-Term Care	HQO's Evidence Development and Standards division (Province) London Health Sciences center/High Impact Technology Evaluation (Hospital) Programs for Assessment of Technology in Health)/McMaster University (Province) Toronto Health Economics and Technology Assessment Collaborative/University of Toronto (Province) Technology Assessment at Sick Kids /Toronto Sick Kids Hospital (Hospital) The Ottawa Hospital Technology Assessment Program (Hospital)
Prince Edward Island	Health PEI	None
Quebec	Ministry of Health and Social Services	Institut national d'excellence en santé et en services sociaux (INESSS, Province) Technology Assessment Unit McGill University Health Center (Hospital) Centre hospitalier universitaire de Sherbrooke(Hospital) Direction de l'évaluation des technologies et des modes d'intervention en santé/Centre hospitalier universitaire de l'Université de Montréal (Hospital) Centre hospitalier universitaire Sainte-Justine(Hospital) Centre hospitalier universitaire de Québec(Hospital)
Saskatchewan	Ministry of Health	None*
Northwest Territories	Health and Social Services	None
Yukon	Health and Social Services	None

* There are some bodies, such as the Manitoba Centre for Health Policy Research, the Saskatchewan Health Quality Council, or Ontario's Institute for Clinical Evaluative Sciences (ICES), which provide some of this function for the province although they are not officially viewed as "HTA" bodies.

Source: Husereau (2011a), with modifications.

of HTA in informing purchasing decisions for our healthcare system, most Canadians likely are unaware of the role economic evaluation plays in this process and are unlikely to have much knowledge of the existing use of national and local HTA economic evaluations and barriers to their use (Lehoux et al. 2003).

Experience Abroad: Lessons for Canada

The use of HTA in other countries highlights several important lessons for Canada when managing new technology with uncertain consequences.

Beyond Information: Linking HTA to Budgets and Technology Management

One of the most important measures for promoting economic evaluation and ensuring that healthcare system spending remains sustainable is to create incentives that discourage overspending. Two healthcare systems that have employed strict spending caps are Israel and New Zealand. Israel has a legally binding list of covered health services (the health services basket, or HSB) that the minister of health may expand only if it does not increase costs. The rule is that, "New services may not be added unless a source of funding is found." This has created a need for rigorous economic evaluation and greater accountability for projecting the impact of new technology on future costs.

Similarly, New Zealand's Pharmaceutical Management Agency (PHARMAC) has a budget whose growth is capped by standard inflationary increases to create an environment for rigorous decisionmaking. Techniques to estimate maximum efficiency for allocating resources (e.g., league tables and program-budgeting marginal analysis) are then used to scrutinize drug-budget costs. The resulting information can further inform price consultation and create a strong signal to innovators regarding the need for new cost-effective drugs in particular areas.[11] Fixed budgets also provide opportunities for HTA bodies to re-assess older technology, as a way of limiting unnecessary expenditures on obsolescent or low-value technology.

As noted above, another approach to ensuring sustainable cost increases is to create price-volume agreements with producers. For example, Australia has price-volume agreements for diagnostic imaging and anaesthetics. Under these arrangements, the government, producers and professional groups agree, in advance, that expenditures on a particular technology will be limited to a predetermined amount over three to five years. If technology use under the agreement is higher than anticipated, prices per use fall accordingly to keep within the ceiling. Similarly, when utilization of a technology is lower than expected, prices can rise. But when new, cost-increasing technologies are approved, the three-to-five-year spending cap is re-estimated.

The primary benefit of price-volume agreements for governments is that they create cost certainty regarding the introduction of a technology over a set period of time. For technology suppliers, these agreements create revenue certainty and a focus on variable costs. Over time, these arrangements can be renegotiated based on new evidence of a technology's effectiveness.

11 New Zealand's fixed budget is often referred to as an "indicative" budget, as bids to increase it can happen every budget cycle, though for any given year the budget helps determine the maximum acceptable treatment cost for a given health outcome. The oft-mentioned concern in this framework is related to balancing cost containment against incentives for innovation, as discussed in Box 1. For example, does one invest in small improvements in large therapeutic areas or large improvements in small ones?

In Canada, price-volume agreements are commonplace for drugs paid by provincial plans, but there are opportunities to implement this approach for medical device procurement. Typically, hospital decisions to adopt new medical devices are made by senior administrators and medical leaders who consider clinical value. However, the actual procurement decisions are made elsewhere by individual finance departments or cross-hospital shared service organizations. Approaches to medical-device procurement are similar to those for non-health commodities – price deals are sought but without linking procurement strategically to clinical value or medically appropriate utilization rates. Clearly, there are opportunities for HTA to inform such strategic procurement decisions.

HTA and Value-based Pricing

Germany froze existing prices of patented medicines in 2010, and an *Act to Reorganize the Pharmaceuticals' Market in the Statutory Health Insurance System* came into effect a year later. The resulting German value-based pricing system relies on economic evaluations and, as in Canada, works within a highly decentralized health system. But the German approach differs in important ways. For instance, one body negotiates prices on behalf of 300 health regions (sickness funds) responsible for care delivery, and prices are publicly disclosed.

When a price is agreed upon, it is binding on all sickness and private healthcare funds, yet there are provisions to create separate arrangements with the drug suppliers if an overall agreement has not been reached within a year. Sweden has had a similar system since 2002, centrally negotiating prices on behalf of its many regional (city-based) councils. Australia and France also have central mechanisms to negotiate drug purchases based on economic evaluations.

In Canada, the recent development of a Pan-Canadian Pricing Alliance, combining the purchasing power of provincial and territorial public drug plans, may create the opportunity for increasing the use of HTA economic evaluation. As of October 2013, this provincial-territorial alliance had successfully negotiated at least 23 brand name drug prices on behalf of participating provinces, with further negotiations underway (Alyward and O'Quinn 2013). Participation in the alliance is optional, and any new drug approved by the CDR or pCODR can be considered for negotiation.[12] Yet, the operational details of the economic evaluation techniques that will be used are still under development, and there is no formal operating structure as yet.[13]

Without explicit recognition of a new drug or procedure's costs, its actual use in practice and its societal value, there is a potential danger of payer or producer exploitation since the negotiated price will rely more heavily on who is at the table than on an unbiased assessment of the new medicine or medical device. Similar purchasing behaviour occurs at Canadian hospitals and by the group purchasing organizations that often represent them.

Decentralization, Sub-optimization and Duplication

As also noted earlier, more narrowly focused forms of HTA are often undertaken by actors who are responsible for specific types of healthcare costs, not just by system-wide agencies such as in the United Kingdom's NICE. For example, major

12 Until now, participation has been limited to publicly funded plans. An issue for future consideration is whether private insurers should be allowed to join these arrangements, as they are in Germany, for example.

13 For example, it is not clear how HTA relates to pricing decisions or how these decisions link back to estimated health benefits.

British hospitals make HTA choices with respect to what drugs to give to inpatients and what kinds of equipment to buy. As well, many other countries have specialized agencies that conduct HTAs for pharmaceuticals. In federal states where responsibility for managing healthcare rests with sub-national units such as Canada's provinces, there are often several regional agencies engaged in HTA.

While specialization and decentralization can be valuable in developing expertise and responding to local conditions, it can also lead to duplication and wasted resources, as well as inconsistent decisions. The problem of "sub-optimization" is particularly knotty when HTA is performed by agents with responsibility for specific budgets.

Consider the following example: a new in-hospital treatment that may improve patient health and reduce costs by lowering amputation rates and the need for prosthesis and rehabilitation requires an upfront investment. Yet senior hospital administrators responsible for approving such an investment will not realize the savings that would occur outside the hospital, and go to rehabilitation and limb replacement programs – so they have limited incentives to adopt the therapy. Similarly, out-patient drug programs will not see returns in their budgets from reducing expensive hospital admissions.

As these examples show, individual hospital and drug administrators are incented to act according to their particular budget constraints rather than total health system costs. This means public officials in charge of a drug budget may see net opportunity costs represented solely by the cost of implementation and its impact on the use of other drugs, rather than on the full spectrum of societal benefits. An analysis of CDR recommendations to provincial drug plans revealed this is the case, with price (a proxy for budget impact) as one of the most important factors in listing recommendations, next to certainty about effectiveness (Rocchi 2012).

Several highly decentralized countries have attempted to overcome the challenges associated with HTA duplication and inconsistencies related to isolated health budget decisionmaking. In Spain, for example, a crisis in healthcare spending and vast decentralization of HTA activities has led to the consolidation of seven separate HTA agencies into a single network (Agencias y Unidades de Evaluación de las Tecnologias Sanitarias, AUnETS). This effort, together with centralized authority for determining the medicare basket, is a first attempt to improve the use of HTA in Spanish decisionmaking and mimics the United Kingdom's centralized system. The new Spanish approach offers a platform for a consistent notion of value and its associated assessment methods. It may also reduce duplication through enhanced information sharing and opportunities for coordination.

A more ambitious harmonization attempt across agencies exists among several Europe-wide HTAs. The European Union Network of HTA producers (EUNetHTA) was formed in part to reduce duplication and provide more consistency in evaluation of new health technologies. These HTA agencies collaborate on assessments, share information regarding planned and ongoing projects, develop consistent methods and approaches to assessment, and share information regarding what specific coverage determinations have been made and the impact of their work. This network has in turn been a platform for collaborative initiatives among HTA bodies, regulators, patients and other policy actors.

In Canada, where there are many hospital-specific HTA processes, assessments are primarily concerned with new hospital-based technologies whose costs are expected to fall on the hospital or regional budget. But with little incentive to reduce costs in other non-hospital programs, there may be no impetus to take into account system- or society-wide costs through economic evaluation. The same may be true for wider societal benefits including productivity gains such as returning patients sooner to work.

There may be opportunities for provinces to address these problems by more coordination of hospital and provincial payer decisions. For example, provinces should consider mechanisms to provide additional funding to hospitals for technologies when there is clear evidence that adopting them would reduce costs outside of hospital budgets.

New Approaches to the HTA Process

Given the conflicting interests of technology developers, patients and taxpayers, it is inevitable that centralized HTA assessments are somewhat adversarial in nature. However, the stakes are high, and the costs of delay in introducing effective new drugs, treatment methods and medical devices can be considerable. As a consequence, some healthcare systems have attempted to make the HTA process less adversarial and more constructive. The hope is that by moving in this direction, the assessment process will be speeded up by being more flexible and more likely to yield a compromise among competing interests.

For example, Scotland has established a medicines consortium to facilitate the decisionmaking process for introducing new medicines. Full voting members include clinicians, academics, health-system administrators, members of the public and representatives of the pharmaceutical industry. As in many HTA organizations, patients are also engaged and consulted in this process. Other countries are quickly realizing that multi-stakeholder engagement is crucial. In Ireland, for example, despite having excellent (arguably the best) engagement with industry stakeholders, a failure to consult patients on a melanoma drug led to intensive media attention, lobbying by some patient groups and an overturning of their national HTA authority's recommendations.

In Canada, the Ontario Health Technology Assessment Committee also tries to involve an appropriate group of stakeholders. Hopefully this approach will help deflate rhetoric about what investments are appropriate and create some degree of mutual accountability for the healthcare system's sustainability. This, in turn, would increase demand for carefully considered assessments of cost impacts.

Other examples of constructive processes to encourage mutual accountability include early engagement among producers, payers and health providers to promote and monitor the entry of technology into the healthcare system. Early dialogue among HTA bodies, regulators, consumers and manufacturers can help each party better understand the challenges of introducing innovative technology. Notable positive examples of such early dialogue processes for medical devices exist in Europe, especially the UK NICE' s Scientific Advice Programme and the EMA-EUNetHTA Early Dialogue Procedures.

Another example is the Massachusetts Institute of Technology New Drug Development Paradigms (NEWDIGS) program, which has engaged regulators, payers and providers in novel approaches to providing access to new drugs while ensuring value from more rapid access to them. In a similar manner, some HTA organizations have engaged in parallel submission processes, with regulators and HTA bodies working together to allow manufacturers to apply for an earlier coverage decision.

In a similar vein, a pilot program called the MaRS Excellence in Clinical Innovation and Technology Evaluation (EXCITE) pre-market assessment program has been launched in Ontario. EXCITE facilitates upstream collaboration among the provincial payer, industry, academics and the medical device regulator so that non-drug technologies can be evaluated during pre-market development in order to generate sufficient data for decisions by both the regulator and payer. EXCITE also re-introduces an idea previously known as "constructive" technology assessment intended to cultivate R&D investment and streamline R&D choices intended to produce desirable healthcare system innovations.

CONCLUSIONS AND RECOMMENDATIONS

HTA has emerged throughout the western world as a way to balance demand and supply pressures in considering new healthcare technologies within budgetary-constrained single-payer systems. If well designed, transparent and comprehensive, HTA processes can be an effective tool to support decisionmaking. In Canada, the number of entities engaged in various forms of HTA has been growing, and more and more people in healthcare are becoming exposed to the techniques involved. This progress and capacity growth is encouraging. Rather than the provinces counting on a natural slowing of healthcare costs to relieve fiscal pressures, they would be better off grounding their efforts in clear and coordinated HTA processes that incorporate economic evaluation and meaningful collaborative deliberation based on available evidence. As a result, cost-containment policies can be linked to technology-adoption decisions and the HTA process.

At present, NICE in the UK National Health Service is by far the most advanced example of an attempt to utilize a consistent framework for cost control in a government-funded healthcare system. In Canada, both the provinces and the federal government should give consideration to how the strengths of the NICE model could be adapted for use in our more decentralized system.

As well in Canada, the CDR and pCODR programs have played an important HTA role, and Canadian hospitals and province-wide agencies, particularly in Ontario and Quebec, continue to expand the role of HTA in medical-device purchasing decisions.[14] However, the challenges of providing analyses and recommendations based on limited budget silos rather than on broader societal implications must still be overcome.

To promote more effective use of comprehensive HTAs, one needs broader societal engagement and wider dissemination and public awareness of HTA's role and potential. A promising initiative along these lines is the recent Council of the Federation announcement that there will be broader use of economic-impact-based frameworks for clinical guideline development.

As Canada's and foreign countries' experience shows, HTA activity must be closely linked to payers (and budgets) to have a desirable effect on policy change. The budget caps used in New Zealand and Israel, which are associated with HTA results, help to better control the costs of new technologies. In a similar vein, the three-to-five-year fixed-budget constraints within price-volume agreements used in Australia are concrete measures that provide a framework for cost containment and the appropriate adoption of health-improving technologies.

The current transition toward value-based pricing in the United Kingdom is another positive example of how HTA economic evaluation can be used to inform technology adoption in a more constructive way than the traditional "yes" or "no" recommendations. Meanwhile, value-based pricing can make the HTA process less adversarial. Canada would do well to move in this direction and create greater awareness that HTA can produce an implicit measure of society's willingness to pay for health benefits from new technologies, as well as from existing ones. HTAs provide a framework that makes it easier to reach compromises in negotiations involving industry, payers and patients regarding the introduction of new expensive

14 McGregor (2003), for example, reported cost savings of $3 million per year in a single hospital with widespread support due to participation from administrators, clinicians, academics and other key hospital stakeholders.

technologies for serious illnesses. HTA is here to stay, and its scope could include evaluating a broader set of healthcare procedures, in addition to drugs and devices, to encourage better value for money.

The use of HTAs as a way to set a price government is willing to pay for a certain technology should be promoted by provinces, preferably within the Pan-Canadian Pricing Alliance and other strategic purchasing initiatives. And in moving forward, there should be a transparent way to show and evaluate how HTAs are used and their role in final decisions.

As it evolves, the Pan-Canadian Pricing Alliance should also strive to reduce duplication and consider volume effects. Currently, prices often are negotiated without explicitly considering utilization, and once a price is reached, industry still has to go to each participating insurer to obtain further agreement. This extra step creates inefficiency and may lead to a wider range of technology-adoption decisions among the provinces as they seek more information relative to their unique budgetary constraints and price-negotiation position.

Both the provinces and Ottawa have much to learn from the HTA experience outside Canada. Canadian agencies should draw as much as possible on evaluations and evidence produced elsewhere – from randomized clinical trials, post-market assessments, clinical guidelines, etc. – and maintain close relationships with international organizations and their counterparts in other countries.

Finally, HTA frameworks in Canada also must aim to encourage greater stakeholder participation and relationship development. While there are examples of progress, one could involve a broader range of actors such as patient and industry umbrella groups, along with other key stakeholders such as providers and the public (taxpayers). To be effective, HTA must be conducted in a neutral manner and be reasonably immune from politics, public pressure and media advocacy. It is an important policy tool to make decisions based on what is known and what is feasible, rather than what is desired – an instrument that more effectively brings evidence and social values to bear on what are often thorny decisions.

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